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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/620,071 | 07/15/2003 | Bruce R. Davis | 38190/259583 | 7115 |
| 826 | 7590 | 09/19/2006 | EXAMINER | |
| ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000 | | | | GORDON, BRIAN R |
| ART UNIT | | PAPER NUMBER | | |
| | | 1743 | | |

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/620,071 | DAVIS ET AL. | |
| | Examiner | Art Unit | |
| | Brian R. Gordon | 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 7-15-03.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-27 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 2 and 3, it is unclear if applicant intends for the exhaust outlet and source of rinse fluid to be considered as an elements of the apparatus. As presently drafted the claim does not positively claim the element as such.

As to claim 3, the examiner suggests amending the claim to recite, "further comprising a source of rinse fluid connected to a rinse fluid input port of at least one of the first and second selection valves.

Furthermore a number of the apparatus claims employ a number of "configured to" phrases which express and intended function of the elements. For example, see claim 10, it appears as if the claim should read, wherein the processing device comprises an Ethernet port for communicating the chemical characteristic from the analysis device.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1- 11, 13-15, and 17-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Afeyan et al., US 6,344,172.

Afeyan et al. disclose method of using an analysis system the includes multiple valves, pumps, detectors, and solution reservoirs.

The device includes first and second selection valves (116, 112) with multiple ports and respective outlets (see col. 8, line 53 – col. line 13), fluid injection valves (131, 132), sample vessels (131, 132), and analysis device (UV absorbance detector 136) (see figure 3; col. 10, lines 8-54), multiple pumps (113, 119, and others not labeled).

Valves 134 and 133 may also be configured so as to permit passage of effluent or eluant from second system column 132 to waste or to detector 136 (exhaust outlet/port).

As to claims 3-5, the claims employ “configured to” phrases, as such the source of rinse fluid is not considered an element of the invention. It’s on required the device be structural capable of allowing for such connections to ports or the valves. One can choose to connect any other element to the ports as so desired.

FIG. 1 is a drawing of a commercial embodiment of the invention, which shows the protein separation apparatus of the invention substantially enclosed in a housing, along with a computer keyboard, mouse, and terminal in which data is collected and stored, and in which program control sequences are stored and executed.

Afeyan et al. discloses a calibration method. The device is calibrated by passing through the solute detector known concentrations of pure target solute so that concentration units can be correlated directly with, e.g., absorbance units (col. 24, 9-12).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afeyan as applied to claims 1- 11, 13-15, and 17-27 above, and further in view of Hanson et al. US 4,108,602.

Afeyan does not disclose the device as comprising a bubble detector.

Afeyan does disclose the device including a switching means for cleaning and the desire to purge the sample line.

Hanson et al. discloses automated multiple sample chemical testing method and apparatus of the character wherein air pressure purging is employed, a to minimize interference with sample detection from the presence of bubbles or foam which tend to be generated during any such air pressure purging.

As such it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Afeyan to detect bubbles which may arise from the cleaning process. Detection of such bubbles would allow for preventive measures to be taken to ensure the bubbles do not interfere with the sample detection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sanuki; Sannosuke; Brink, Peter John van den et al.; Anderson; Marc R. et al.; Wilson; Ronnie E.; Yoshida; Kasumi et al.; Borade, Ramesh et al.; Coasssin; Peter J.; Smith, Michael E. et al.; Guan; Shenheng et al.; Carver, Jr.; Edward

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Lawrence et al.; Binder; Steven R. et al.; Bussmann; Egon et al.; and Choi; Sun et al. disclose analytical devices including valves.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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